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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,257	09/26/2003	Manssur Yalpani	CRB-T103X	8838

7590 03/06/2006
MANSSUR YALPANI
6324 FERRIS SQUARE
SAN DIEGO, CA 92121

EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,257

Applicant(s)

YALPANI, MANSSUR

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4-7 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants election of Group 2 (claims 4-7) is acknowledged.

An "election of species" requirement is now imposed, as set forth below.

First, however, the meaning of the terms "poly-*alpha*-glutamic acid *per se*" and "poly-*gamma*-glutamic acid *per se*" is explained.

The term "poly-*alpha*-glutamic acid *per se*" is used hereinbelow in accordance with the conventional meaning of this term, i.e., a compound of formula I (claim 5) in which X is hydrogen, Z is -OH (and "Y" is not hydrogen), "n" is 2 and R is carboxy. Similarly, the term "poly-*gamma*-glutamic acid *per se*" refers to a compound of formula II in which X is hydrogen, Z is -OH (and "Y" is not hydrogen), and R is -COOH. The foregoing terms do not include metal ion salts.



Applicants are required under 35 U.S.C. §121 to elect disclosed species/subgenera (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

a) one of the following: (i) poly-*alpha*-glutamic acid *per se* is administered, and poly-*gamma*-glutamic acid *per se* is not administered, (ii) poly-*gamma*-glutamic acid *per se* is administered, and poly-*alpha*-glutamic acid *per se* is not administered, (iii) a mixture of poly-*alpha*-glutamic acid *per se* and poly-*gamma*-glutamic acid *per se* is administered, or (iv) poly-*alpha*-glutamic acid *per se* is not administered, and poly-*gamma*-glutamic acid *per se* is also not administered;

- b) one of the following: (i) at least one compound other than (or in addition to) poly-*alpha*-glutamic acid *per se* and poly-*gamma*-glutamic acid *per se* is administered, or (ii) no compound other than poly-*alpha*-glutamic acid *per se* and/or poly-*gamma*-glutamic acid *per se* is administered;
- c) in the event that at least one compound other than (or in addition to) poly-*alpha*-glutamic acid *per se* and poly-*gamma*-glutamic acid *per se* is administered what are the compounds that are administered?
- d) the molecular weight of the polyglutamic polymer, or if a range of molecular weights is administered the molecular weight of one of those poly-Glu polymers.;
- e) the approximate polydispersity of the polyglutamate polymer.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER